

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DIOMED, INC.

Civil Action No. 04-CV-10444-RGS

Plaintiff,

v.

VASCULAR SOLUTIONS, INC.
Defendant.

**DEFENDANT VASCULAR
SOLUTIONS, INC.'S
CLAIM CONSTRUCTION
MEMORANDUM**

INTRODUCTION

Plaintiff Diomed, Inc. ("Diomed") alleges that Defendant Vascular Solutions, Inc. ("VSI") infringes Claims 9-14, 16-19 and 21 of Diomed's United States Patent No. 6,398,777B1 (the "'777 Patent"). The controversy between the parties centers on Claim 9.¹

A method of treating a blood vessel using laser energy, comprising the steps of:

inserting means for emitting laser energy into the blood vessel at a puncture site, wherein said emitting means has a laser emitting section;

placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site; and

emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of said blood vessel.

The proper construction of these claim limitations is as follows:

1) "means for emitting laser energy" means a fiber optic line with an uncoated, rounded tip and its equivalents, as that is the only structure disclosed in the specification for performing the claimed function. The "laser emitting section" is part of the "means," and refers to the uncoated, rounded tip of the fiber optic line.

2) "placing said laser emitting section ... into intraluminal contact with the blood vessel" requires a deliberate act to "place" the uncoated rounded tip of the fiber optic line into physical

contact with the interior blood vessel wall. The ordinary meaning of the term “placing” requires a deliberate act, and that ordinary meaning is confirmed by the patent specification and file history. In addition, the patent specification and file history require construing “placing … into intraluminal contact” to mean draining the blood and applying compression to the blood vessel to achieve intraluminal contact.

3) “emitting said laser energy into the blood vessel” means delivery of the laser energy to the blood vessel wall during intraluminal contact. That is the ordinary meaning of the phrase “into the blood vessel,” and that meaning is confirmed by the patent specification and file history.

In Diomed’s view, by contrast, *any* contact between the uncoated tip of the fiber optic line and the blood vessel wall, no matter how inadvertent or fleeting, meets the “placing … into intraluminal contact” limitation. Diomed also contends that the “emitting said laser energy into the blood vessel” limitation does not require delivery of laser energy while the fiber optic tip is in intraluminal contact with the blood vessel wall. As will be explained in depth below, Diomed’s proposed constructions conflict with the ordinary meaning of the claim terms and contradict the statements made in the specification and file history to obtain the ‘777 Patent. VSI therefore respectfully requests that the Court adopt its claim construction.

STATEMENT OF THE CASE

A. THE PRIOR ART

1. Goldman U.S. Patent No. 4,564,011 (1986)

The Goldman patent describes inserting a fiber optic line into a blood vessel. The physician then applies pressure a short distance away from the fiber optic probe in the direction of the blood flow, to constrict the blood vessel and prevent the flow of blood. The laser energy is then transmitted through the fiber optic line into the blood vessel. The laser energy causes the

¹ The remaining asserted claims either depend from Claim 9 (claims 10-14 and 16-20) or

formation of a blood clot, and, by moving the laser up or down the blood vessel, the clotting can be extended throughout the blood vessel. Goldman Patent, (Vitt Dec. Ex. 3).

2. Trelles U.S. Patent No. 5,531,739 (1996)

The Trelles patent also describes a method for treating blood vessels using laser energy. In Trelles, the fiber optic probe is positioned underneath the blood vessel. The blood vessel is then treated with laser energy all along its length so that the blood vessel collapses. See Trelles Patent, Col. 1-3, (Vitt. Dec. Ex. 4).

3. Biegeleisen Patent No. 5,022,399 (1991) and Article (1989)

Dr. Ken Biegeleisen is the inventor and author of two references relevant to the '777 Patent: U.S. Patent No. 5,022,399, applied for on May 10, 1989, and issued on June 11, 1991, and an article titled "Use of the Venoscope for the Treatment of Varicose Veins." (Vitt Dec. Exs. 5 and 6). The Biegeleisen patent describes the use of a "venoscope" to treat varicose veins. Specifically, the patent describes inserting a flexible catheter with fiber optic bundles into the varicose vein. The fiber optics are used to visualize the interior of the varicose vein, and monitor the blood flow inside the vein to assure the proper positioning of the catheter. In the method described in the Biegeleisen patent, the venoscope is then used to direct one of three possible treatment methods to varicose vein: (1) a chemical solution, called a sclerosant, to collapse the vein; (2) use of a laser to therapeutically cauterize the inner lining of the vein; or (3) use of electro-cauterization to treat the vein. The Biegeleisen article, like the Biegeleisen patent, describes the use of a laser as part of the venoscope as a "cauterizing agent" to treat varicose veins.²

incorporate all of its limitations (claim 21).

² One of the Diomed inventors, Dr. Salat, knew about but did not disclose the Biegeleisen article to the Patent Office. That failure to disclose is the basis for defendants' inequitable conduct defense.

B. DIOMED'S '777 PATENT SPECIFICATION AND FILE HISTORY

1. The '777 Patent Specification

The '777 Patent specification describes a method of treating a blood vessel involving a series of specific steps:

- 1) A fiber optic line with an uncoated, rounded tip is inserted into a blood vessel and advanced inside the vessel to the treatment site.
- 2) The blood vessel is emptied of blood.
- 3) Compression is applied to the blood vessel, either manually or with an ultrasound probe, to insure that the fiber optic tip is in physical contact with the blood vessel wall. The '777 Patent refers to this physical contact of the fiber optic tip and the blood vessel wall as "intraluminal contact." The '777 Patent also describes the drainage of blood and compression of the blood vessel as "important" to "insure direct contact of the vessel walls with tip 41 during delivery of laser energy." '777 Patent Col. 6 (Vitt Dec. Ex. 1).
- 4) Laser energy is applied to the blood vessel wall during intraluminal contact.
- 5) The fiber optic line is withdrawn, with compression on the blood vessel being maintained to insure continued intraluminal contact. '777 Patent, Cols. 3-6 (Vitt Dec. Ex. 1).

The result of this procedure, according to the '777 Patent, is to cause damage, or fibrosis, of the blood vessel wall.

2. The '777 Patent File History

The inventors filed the patent application that became the '777 Patent on August 13, 1999. See '777 File History (Vitt Dec. Ex. 2). In an office action dated November 15, 2000, the patent examiner rejected the principal device claim, Claim 1, and the principal method claim, Claim 9, because they were anticipated by the Goldman Patent. Id., pp. 70-71.

In response, the '777 Patent inventors told the Patent Office that "the device according to the claimed invention is arranged inside the vein to be treated and then the laser is directed

against a wall of the vein to thereby cause fibrosis of the vein leading to a decrease in the diameter of the vein. (See specification p. 8, lines 16-28.)” Id. at 83-84. The statement that “the device according to the claimed invention is arranged inside the vein” refers to what became Col. 3, lines 56-67 and Figs. 9-13 of the issued patent. The reference describes the draining of blood and application of compression to insure intraluminal contact during the delivery of laser energy. See ‘777 Patent, Col. 3 l. 56-67 and Figs. 9-13 and ‘777 File History, pp. 29 (Vitt Dec. Exs. 1-2).

The inventors then distinguished Goldman and argued for the patentability of Claim 1 and Claim 9 with the following arguments:

- [Goldman] “is not adapted to deliver energy **to the vein wall in an intraluminal manner to thereby decrease the diameter of the vein.**”
- [In Goldman] “the laser energy is not directed into the wall of the blood vessel but rather is **used to create a blood clot in the vessel.** Accordingly, unlike the claimed invention, there is no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall to thereby cause a decrease in the size of the vessel.”
- “Independent claim 9 recites a method in which laser emitting means is placed in **intraluminal contact** with a blood vessel and laser energy is directed **into the blood vessel wall** to thereby decrease the diameter of the vessel. As discussed above with respect to the claim 1 the Goldman reference fails to teach any such method.”

File History, pp. 84-85 (Vitt Dec. Ex. 2)(emphasis in original).

Given the claim construction issues in this case, two points deserve emphasis. First, to distinguish Goldman, the ‘777 Patent inventors described their *invention* as requiring the draining of blood and application of compression to insure intraluminal contact. Second, the inventors repeatedly distinguished Goldman by stressing that the ‘777 Patent method requires “intraluminal contact” and delivery of laser energy directly to the blood vessel wall “in an intraluminal manner,” rather than delivery of laser energy into the blood itself to create a blood clot. These arguments were successful, and the Patent Office issued the ‘777 Patent without requiring any amendment to Claim 9.

ARGUMENT

I. THE LAW OF CLAIM CONSTRUCTION

The construction of patent claims is a question of law for the Court. Markman v. Westview Instruments, Inc., 52 F.3d 967 Fed. Cir. 1995 (en banc), affirmed 517 U.S. 370 (1996). The Court's task is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. See Bell Atlantic Network Serv., Inc. v. Covad Comm. Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001).

The Federal Circuit has instructed that claim terms are to be given their ordinary and accustomed meaning. See Bell Atlantic, 262 F.3d at 1267. The Federal Circuit has, however, been less than perfectly clear in instructing district courts how they are supposed to determine what that ordinary and accustomed meaning is, and when district courts should deviate from ordinary meaning based on statements in the patent specification or file history. Cf., e.g., Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002) with Phillips v. AWH Corp., 363 F.3d 1207 (Fed. Cir. 2004), vacated and en banc rehearing granted July 21, 2004 and Bell Atlantic.³

The principal current controversy is the relative importance to be given to the intrinsic evidence (the specification and file history) and to dictionaries. See Texas Digital. It has long been the law, as the Federal Circuit held, sitting en banc, in the Markman case, that the "claims must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 979. The Federal Circuit stressed in Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996) that the specification is "always highly relevant to the claim construction analysis" and is the "single best guide to the meaning of a disputed term." Id. at 1582; see also Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

³ A copy of the Federal Circuit order granting *en banc* rehearing of the Phillips case is Exhibit xx to the Vitt Declaration.

In the Texas Digital case, a panel of the Federal Circuit attempted to reorder the hierarchy of evidence relevant to patent claim construction. In brief summary, the Texas Digital panel instructed district court judges to first consult dictionaries, encyclopedias or treatises to attempt to determine the “ordinary meaning” of the patent claim terms in dispute. Id. at 1203-1205. The Texas Digital court made clear that the patent specification and the file history must also be consulted in every case, but only after attempting to determine the “ordinary and customary meaning” from other sources. Id.

The Federal Circuit recently granted a petition for en banc rehearing in the case of Phillips v. AWH Corporation, 363 F.3d 1207 (Fed. Cir. 2004) to consider these questions. (Vitt. Dec. Ex. 12). Claim construction law, at least as it relates to the hierarchy of evidence, is therefore currently uncertain. Despite this uncertainty, the current state of the law can be reasonably synthesized as follows.

Claim terms should be given their ordinary and customary meaning as they would be understood by a person of ordinary skill in the art. Dictionaries, encyclopedias and treatises are currently favored sources for determining that ordinary meaning. The patent specification and the file history must always be reviewed, for several reasons. First, the definition of claim terms may not be sufficiently clear to give fair notice of the scope of the claims, even after review of dictionary definitions; the Court must then look to the specification and file history to ascertain the meaning of claim terms as used in the context of the invention. See, e.g., Bell Atlantic, 262 F.3d at 1268; Comark Comm. v Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998). Second, the court must examine the patent specification and file history to determine whether the patentee has chosen to “act as his own lexicographer” and define a term, either expressly or by implication, in a way different than the ordinary meaning. Bell Atlantic, 262 F.3d at 1268. Third, the district court should determine whether there has been a clear disavowal of claim scope in the specification or file history. Id. Examples of situations where the patent

specification or file history require a deviation from “ordinary meaning” include where the patent applicant consistently uses a term either more or less expansively than its ordinary meaning, see Alloc, 342 F.3d at 1368, or where the patent applicant has described a particular embodiment as “important to the invention.” See Phillips, 363 F.3d at 1213, quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002).

The Court need not be overly concerned here with the state of flux in claim construction law, however. In this case, the “ordinary meaning” of the disputed claim terms is clear and confirmed by the specification and file history. In the single case where defendant proposes a slight deviation from “ordinary meaning,” concerning the meaning of “placing … into intraluminal contact,” the statements in the file history and the specification are clear.

II. DEFENDANTS’ CONSTRUCTION OF CLAIM 9 SHOULD BE ADOPTED.

A. “inserting means for emitting laser energy into the blood vessel at a puncture site, wherein said emitting means has a laser emitting section”

The construction of a means-plus-function limitation is a two-step process. First, the District Court must identify the claimed function. Second, the District Court must identify the corresponding structure in the written description that performs the claimed function. Omega Eng’g, Inc. v. Raytek Corp., 334 F.3d 1314, 1321 (Fed. Cir. 2003); Micro-Chem, Inc. v. Great Plains Chem. Co., Inc., 194 F.3d 1250, 1258 (Fed. Cir. 1999). The means-plus-function claim limitation covers the disclosed structure and its equivalents. 35 U.S.C. § 112(6).

In this case, the claimed function is “emitting laser energy into the blood vessel...” The ‘777 Patent discloses a single structure for performing the function of “emitting laser energy”: a fiber optic line with an uncoated, rounded tip. See ‘777 Patent, Col. 4 (Vitt Dec. Ex. 1). The ‘777 Patent describes the structure as follows: “Fiber optic line 40 has a tip 41 that is uncoated so as to allow emittance of laser energy. … The tip of fiber optic line 40 is preferably rounded in shape, although other shapes are contemplated.” Id., Col. 4 l. 52-60. The ‘777 Patent cites the rounded tip as advantageous for the emission of laser energy, stating that “the rounded tip 41 is

preferred because it enables the operator to more easily control the amount of vein to be treated..." Id., Col. 4 l. 60-62.

Although the '777 Patent says that "other shapes are contemplated," no shapes other than the rounded tip are disclosed. There is no basis, therefore, for the Court to expand the corresponding "structure" to include those undisclosed and unknown shapes. See Omega, 334 F.3d at 1321 (corresponding structure must be disclosed and must also be "clearly linked" to the claimed function). The Court should therefore construe the claim term "means for emitting laser energy" to mean a fiber optic line with an uncoated, rounded tip and its equivalents.

This claim limitation concludes with the phrase "wherein said emitting means has a laser emitting section." The "laser emitting section" is a portion of the "means for emitting laser energy," and refers to the uncoated, rounded tip of the fiber optic line from which the laser energy is "emitted." '777 Patent Col. 4 l. 52-60 (Vitt Dec. Ex. 1). The rest of the fiber optic line is coated to prevent the emission of laser energy. Id. at Col. 4 l. 55-56.

B. "placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site"

The parties agree that the term "intraluminal contact" requires physical contact by the uncoated tip of the fiber optic line with the interior blood vessel wall. (Vitt Dec. Exs. 9-11). The dispute is over what "placing" the laser emitting section "into intraluminal contact" means.

Defendants contend that the ordinary meaning of "placing ... into intraluminal contact" requires a deliberate act. Defendants contend also that the patent specification and file history require not just any deliberate act, but specifically require draining the blood and applying compression to the vessel to insure intraluminal contact.

By contrast, Diomed contends that the limitation reaches *any* contact of the uncoated tip of the fiber and the blood vessel wall, even if the contact is incidental, brief, and unintentional. The plain meaning of the word "placing," the clear statements in the patent specification, and the arguments made in the file history show that Defendants are correct and that Diomed is wrong.

The plain meaning of “placing” is “to put or set in a particular place, position, or situation. . . .” See Dictionary Definitions (Vitt Dec. Ex. 8). “Placing” therefore involves a deliberate, intentional act; one cannot inadvertently put something in a *particular* place.

The case of Combined Systems, Inc. v. Defense Technology Corp., 350 F.3d 1207 (Fed. Cir. 2003) is instructive here. In that case, the patent claim required “forming folds” in a tubular sock holding the projectile body before it was inserted into a shell. The patent holder argued that “deliberate and systematic” formation of folds was not required, and that the patent claim reached any formation of folds that occurred before, during, or after insertion. The Federal Circuit rejected this construction, ruling that the ordinary meaning of “forming folds” required the “deliberate and systematic” formation of folds, and did not reach the incidental forming of folds during insertion. Id. at 1210-11. This Court should construe the “placing . . . into intraluminal contact” limitation just as the Federal Circuit construed the “forming folds” limitation in Combined Systems: to require a deliberate and intentional act of placing the fiber optic tip into intraluminal contact with the blood vessel wall.

The ‘777 Patent specification confirms that the method claimed in Claim 9 requires deliberate and intentional “placing” of the fiber optic tip into intraluminal contact. Indeed, the patent specification makes clear that this limitation requires draining the blood and applying compression to insure that intraluminal contact.

It is important to remember that delivery of laser energy into the blood vessel wall via intraluminal contact is central to the claimed invention. The ‘777 Patent inventors repeatedly distinguished the Goldman patent and other prior art by stressing the importance of intraluminal contact and the delivery of laser energy directly into the blood vessel wall. See ‘777 Patent Col. 2 and File History pp. 83-84 (Vitt Dec. Exs. 1-2). The ‘777 Patent inventors emphasized that their method was very different from the Goldman Patent method of delivering laser energy *into the blood* to form a blood clot. Instead, the ‘777 Patent method seeks to *avoid* blood clots, and

instead cause fibrosis of the blood vessel wall. The ‘777 Patent’s method achieves this by draining the blood and applying compression to insure intraluminal contact and the delivery of laser energy into the blood vessel wall.

Given the centrality of intraluminal contact to the claimed invention, the statements in the ‘777 Patent specification concerning how to achieve intraluminal contact make the meaning of this limitation very, very clear to a person of ordinary skill in the art. The ‘777 Patent describes only one method of achieving intraluminal contact: draining blood and applying compression to the blood vessel. No other technique of “placing … into intraluminal contact” is described. The enablement requirement of Section 112(1) requires the ‘777 Patent inventors to provide a description of the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same.” Id. Any construction of “placing … into intraluminal contact” broader than draining the blood and applying compression is thus invalid because it is not enabled. See Liebel Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004)(court should construe claims to preserve validity if plausible valid construction is available).

Not only is draining and compression the *only* method described, the ‘777 Patent specification describes those steps as *important* to *insure* intraluminal contact. The abstract of the ‘777 Patent, describing the invention, states that: “The vein will be emptied of blood using elevation of the limb, patient positioning, compression, or other means”— “emptying” is not optional. Further, the specification emphasizes that draining the blood and applying compression is essential to insure intraluminal contact:

- In Column 5, the ‘777 Patent states: “After being emptied of blood, greater saphenous vein 30 is also compressed, preferably by hand 44 or by ultrasound imager 42, so that tip 41 of fiber optic line 40 makes direct contact with the vein wall.
- Column 5 later states that “the compression of greater saphenous vein 30 around tip 41 is maintained as fiber optic line 40 is withdrawn. This

method insures damage to the entire thickness of the vein wall of greater saphenous vein 30, ultimately resulting in fibrosis of the vein wall.

- In Column 6, the '777 Patent states that: “As illustrated in Fig. 13, leg 10 is then elevated and lesser saphenous vein 50 is drained of blood and compressed. *The drainage of blood is important to insure direct contact of the vessel walls with tip 41 during delivery of laser energy.*”
- In Column 6, the '777 Patent states that: “vein 54 is emptied of blood and compressed *to insure direct contact of the vessel walls with tip 41 during delivery of laser energy.*”

'777 Patent, Col. 5, l. 12-17 and l. 26-31, Col. 6 l. 9-13 and l. 42-46 (emphasis added) (Vitt. Dec Ex. 1).

Many Federal Circuit cases confirm that these types of statements in the patent specification require interpretation of the “placing … into intraluminal contact” limitation to require draining of the blood and applying compression.⁴ See, e.g., Bell Atlantic, 262 F.3d at 1266-68 (rejecting patentee’s broad construction of term “plurality of different modes” because patentee had consistently used the term more narrowly in the patent specification); Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1350-51 (Fed. Cir. 2004) (limiting patent claim terms “sending,” “transmitting,” and “receiving” to communications over a telephone line because of patentee’s usage in specification); Wang Labs, Inc. v. America Online, Inc., 197 F.3d 1377 (Fed. Cir. 1999)(construing claim term “frame” more narrowly than ordinary meaning because specification described only character-based protocols); Toro Co. v. White Consolidated Ind., Inc., 199 F.3d 1295, 1301 (Fed. Cir. 1999)(construing the claim term “including” more narrowly than ordinary meaning, to require attachment, because patent specification emphasized the importance of attachment).

⁴ Diomed will argue that Defendants are improperly importing limitations from the specification into the patent claim, and that Defendants’ construction violates the doctrine of claim differentiation because dependent claims 10 and 17 add the limitations of draining the blood and applying compression. Both of those arguments fail, given the clarity of the statements in the specification and file history. See Toro Co. v. White Consolidated Ind., Inc., 199 F.3d 1295, 1301-02 (Fed. Cir. 1999)

The ‘777 Patent file history also requires construing “placing … into intraluminal contact” to mean draining the blood and applying compression. In arguing to overcome the Goldman reference, the ‘777 Patent inventors described their *invention* as involving the draining of blood and application of compression to insure intraluminal contact during the delivery of laser energy. File History, pp. 81-85 (Vitt Dec. Ex. 2). The ‘777 Patent inventors pointed out that Goldman involved the delivery of laser energy into the blood “to create a blood clot in the vessel.” Id. The ‘777 inventors argued that, instead of creating blood clots inside the vessel, the ‘777 Patent method involves the delivery of energy directly to the blood vessel wall, during intraluminal contact, to cause fibrosis of the blood vessel itself. Id.

The ‘777 Patent inventors argued that Goldman, unlike their invention, was not “adapted to deliver energy **to the vein wall in an intraluminal manner to thereby decrease the diameter of the vein.**” Id., p. 84 (emphasis in original). They further distinguished Goldman on the grounds that, “unlike the claimed invention, there is no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall to thereby cause a decrease in the size of the vessel.” Id.

This is a clear case of prosecution history disclaimer. See Omega Eng’g, 334 F.3d at 1323-24; Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). The person of ordinary skill reading the file history would understand that the *invention* requires draining of blood and application of compression to insure intraluminal contact. The claim term “placing … into intraluminal contact” should therefore be construed to require a deliberate act, specifically the draining of blood and application of compression to the blood vessel to insure intraluminal contact.

C. **“emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of said blood vessel”**

Defendants contend that the phrase “emitting said laser energy into the blood vessel” means delivery of the laser energy to the interior blood vessel wall via intraluminal contact. The laser energy is delivered while the tip of the fiber optic line is in physical contact with the blood vessel wall. (Vitt Dec. Exs. 10-11).

Diomed contends that this limitation means “emitting sufficient laser energy at the bare tip of the fiber optic line to cause vessel wall tissue damage (e.g. fibrosis) to lead to a decrease in the diameter of the blood vessel.” Diomed makes no mention of intraluminal contact, and evidently contends that “emitting said laser energy into the blood vessel” does not require intraluminal contact. (Vitt Dec. Ex. 9).

Defendants’ position is correct and Diomed’s should be rejected for several reasons. First, the ordinary meaning of the phrase “into the blood vessel” requires directing the laser energy into the *blood vessel* itself, and not into the empty space inside the vessel or into the blood inside the vessel. The “blood vessel” is the generally cylindrical wall that encloses the interior space where the blood flows; particularly in the context of this patent, the term “blood vessel” cannot be construed to be the space itself or the blood contained within the vessel. See Dictionary Definitions (Vitt. Dec. Ex. 8).

Second, the structure of Claim 9 makes clear that applying the laser energy to the blood vessel wall, during intraluminal contact, is required by the claimed method. Claim 9’s method is sequential, as it requires *first* inserting the fiber optic line into the blood vessel, *then* placing the fiber optic tip into intraluminal contact with the interior blood vessel wall, *and then* applying laser energy to the blood vessel wall. See Combined Sys. 350 F.3d at 1211-12. Indeed, if the laser energy can be delivered “into the blood vessel” without intraluminal contact, Claim 9’s

requirement of “intraluminal contact” makes no sense—why would Claim 9 require the “intraluminal contact” step, if the laser energy is then delivered without intraluminal contact?

Third, the ‘777 Patent specification repeatedly makes clear that the laser energy is applied to the blood vessel wall during intraluminal contact and that this specific procedure is central to the claimed invention. The ‘777 Patent specification distinguishes the prior art, particularly the Goldman patent, which discloses delivering laser energy inside the blood vessel to create a blood clot but does not disclose delivering laser energy via intraluminal contact. See ‘777 Patent Col. 2 (Vitt Dec. Ex. 1).

The ‘777 Patent describes and claims a different, allegedly superior, method, involving delivery of laser energy to the blood vessel wall during intraluminal contact. The purpose of the ‘777 Patent’s method is to cause fibrosis of the blood vessel itself, rather than clotting of the blood inside the vessel. In Column 2, after discussing the prior art, the ‘777 Patent specification states that “a need exists for an endovascular laser treatment of varicose veins using laser energy in order to produce direct endothelial and vein wall damage with subsequent fibrosis.” The ‘777 Patent, in the Summary of The Invention section, proceeds to make crystal clear that the *invention* requires delivery of laser energy “into the blood vessel” during intraluminal contact:

It is still another object of the present invention to provide such *a method that causes direct endothelial and vein wall damage with subsequent fibrosis.*

It is a further object of the present invention to provide such a method that introduces a fiber optic line into the vein lumen *to deliver intraluminal laser energy with direct contact of the tip of the fiber optic line with the vein wall.*

It is yet another object of the present invention to provide such *a method that avoids blood clot formation and maximizes vein wall damage.*

These and any other objects of the present invention are achieved by a method for treating varicose veins using a tipped laser energy carrier to *deliver laser energy into the blood vessel lumen to produce direct endothelial and vein wall damage with subsequent fibrosis.*

‘777 Patent Col. 3 l. 3-17 (emphasis added) (Vitt Dec. Ex. 1).

The remainder of the ‘777 Patent specification also consistently requires delivery of laser energy “into the blood vessel” during intraluminal contact. In Column 5, the ‘777 Patent describes the claimed method as requiring *first* the emptying of blood from the vessel and application of compression “so that tip 41 of fiber optic line 40 makes direct contact with the vein wall. *Then*, laser energy … is delivered in bursts through fiber optic line 40 *into the vein wall.*” Id. at Col. 5 l. 13-18 (emphasis added), see also Col. 5, l. 23-31 and 46-49 (describing how the compression of the vein around the tip of the fiber optic line is maintained as the fiber optic line is withdrawn). In Column 6, the ‘777 Patent states:

As illustrated in Fig. 13, leg 10 is then elevated and lesser saphenous vein 50 is drained of blood and compressed. The drainage of blood is important to insure *direct contact of the vessel walls with tip 41 during delivery of laser energy.*

* * * * *

Then, vein 54 is emptied of blood and compressed to insure *direct contact of the vessel walls with tip 41 during delivery of laser energy.*

Id. at Col. 6, l. 9-13, 43-46 (emphasis added).

Fourth, Diomed disclaimed the claim construction it now advocates during the prosecution of the ‘777 Patent. See Omega, 334 F.3d at 1324; Alloc, 342 F.3d at 1368; Southwall Tech., 54 F.3d at 1576. As discussed above, the Goldman patent disclosed a fiber optic line delivering laser energy inside a blood vessel to create a blood clot. The ‘777 Patent inventors distinguished the Goldman patent by describing their *invention*, in very clear terms, as requiring the delivery of laser energy into the blood vessel wall during intraluminal contact.

In distinguishing Claim 1 from the Goldman patent, the ‘777 Patent inventors made the following argument, which they incorporated into their argument distinguishing Claim 9:

Independent claim 1 recites a blood vessel treatment device including means “adapted for **intraluminal contact** with a wall of a blood vessel, for emitting laser energy to cause **a decrease in the diameter of said blood vessel**”. (emphasis added) Thus the device according to the claimed invention is arranged inside the vein to be treated and then the

laser is directed against a wall of the vein to thereby cause fibrosis of the vein leading to a decrease in the diameter of the vein. (See specification p. 8, lines 16-28). It is respectfully submitted that a close review of the Goldman reference reveals that the device disclosed therein is not adapted to deliver energy **to the vein wall in an intraluminal manner to thereby decrease the diameter of the vein.**

File History, p. 83-84 (Vitt Dec. Ex. 2)(emphasis in original). As discussed above, the statement that “the device according to the claimed *invention* is arranged inside the vein” refers to specification figures that show the draining of blood and the application of compression to insure intraluminal contact “during delivery of laser energy.” See File History, p. 29, which is page 8 of the specification cited to in the file history excerpt quoted above (Vitt Dec. Ex. 2). The ‘777 Patent inventors continued the argument, noting that:

as discussed in the specification of Goldman the laser energy is not directed into the wall of the blood vessel but rather is **used to create a blood clot in the vessel.** Accordingly, unlike the claimed invention, there is no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall to thereby cause a decrease in the size of the vessel.

File History, p. 84 (Vitt Dec. Ex. 2)(emphasis in original).

The ‘777 Patent inventors used the same argument to distinguish Claim 9 from the Goldman Patent:

Independent claim 9 recites a method in which laser emitting means is placed in **intraluminal contact** with a blood vessel and laser energy is directed **into the blood vessel wall** to thereby decrease the diameter of the vessel. As discussed above with respect to the claim 1 the Goldman reference fails to teach any such method.

File History, p. 85 (Vitt Dec. Ex. 2)(emphasis in original).

This is a straightforward case of prosecution history disclaimer. The ‘777 Patent inventors distinguished Goldman patent on the grounds that Goldman did not “deliver energy to the vein wall in an intraluminal manner”; that in Goldman “the laser energy is not directed into the wall of the blood vessel”; that in Goldman there is “no intraluminal contact with the blood vessel nor any delivery of laser energy to the vessel wall”; and that Goldman fails to teach a

method involving “intraluminal contact with a blood vessel and laser energy is directed into the blood vessel wall. . . .” Because of those arguments, the Patent Office granted the ‘777 Patent. The inventors, having used these arguments to obtain the patent, are now bound by them. Defendants’ claim construction is correct, and should be adopted by this Court.

III. DEFENDANTS’ CONSTRUCTION OF THE “EMPTYING THE BLOOD VESSEL” LIMITATION OF CLAIMS 10 AND 21 SHOULD BE ADOPTED.

Claim 10 is a dependent claim, and reads as follows:

10. The method of claim 9, further comprising emptying the blood vessel prior to emitting said laser energy.

‘777 Patent Claim 10 (Vitt Dec. Ex. 1). Claim 21 is an independent claim that adds the “emptying the blood vessel” limitation to Claim 9.

VSI contends that the term “emptying” should be given its ordinary meaning: “Empty” means “containing nothing” and “emptying” means “the act of making empty.” See Dictionary Definitions (Vitt Dec. Ex. 8). Thus Claim 10 should be construed to require the draining of all of the blood from the blood vessel, so that the blood vessel “contains nothing,” that is, is emptied of blood, before the laser energy is applied.

Diomed contends that Claim 10 should be construed to require “removing some or all of the blood from the blood vessel” before applying laser energy. (Vitt Dec. Ex. 9). Thus, according to Diomed, if even “some” of the blood is removed from the vessel, this limitation is met. Diomed evidently plans to argue that the “emptying” limitation is literally infringed if even *one drop* of blood is removed from the blood vessel.

This Court should adopt Defendants’ construction and reject Diomed’s. The ‘777 Patent specification confirms that the ordinary meaning of “emptying” applies here. The ‘777 Patent makes no suggestion that only “some” of the blood should be removed. Instead, the specification repeatedly specifies that the blood should be “drained” from the blood vessel, and

that “the drainage of blood is important to insure” the required intraluminal contact. ‘777 Patent Col. 6, l. 9-13; see also Col. 4, l. 35-37, Col. 5, l. 10-15, Col. 6, l. 43-45 (Vitt Dec. Ex. 1).

IV. DEFENDANTS’ CONSTRUCTION OF CLAIM 19 SHOULD BE ADOPTED.

Claim 19 is a dependent claim, and reads as follows:

The method of claim 9, wherein said laser energy is delivered in bursts.

‘777 Patent Claim 19 (Vitt Dec. Ex. 1). VSI proposed that the “bursts” limitation should be given its ordinary meaning, to mean that the “laser energy is delivered in sudden, intense, and intermittent spurts, or ‘bursts,’ as opposed to steadily and continuously.” (Vitt Dec. Ex. 11). Diomed has not responded. The ‘777 Patent specification is in accord with the ordinary meaning of the term. ‘777 Patent Col. 5, l. 19-24 (Vitt Dec. Ex. 1). VSI’s interpretation should be adopted.

CONCLUSION

For all the foregoing reasons, this Court should adopt Defendants' proposed claim construction.

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Respectfully Submitted,

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